



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22FZ; Docket No. CDC-2022-0075]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled mChoice:

Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings. The collection is part of a research study designed to implement and evaluate the effectiveness of an intervention that utilizes evidence-based education and support tools to improve preexposure prophylaxis (PrEP) adherence among young men who have sex with men (YMSM).

DATES: CDC must receive written comments on or before [INSERT
DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2022-0075 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the *Federal*

Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below. The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project:

mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting approval for 36 months of data collection entitled, "mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings." The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to improve preexposure prophylaxis (PrEP) adherence among young men who have sex with men (YMSM). The goals of this research study are to: 1) improve the overall PrEP experience of providers and YMSM patients; and 2) increase our understanding of provider and patient factors that influence the choice of PrEP regimen by MSM in clinical settings. This study will be carried out in four clinics located in New York, NY (NYC) (two clinics) and Birmingham, AL (two clinics).

Aim 1 of the study will enroll 400 YMSM (ages 18-39) who identify as male, non-binary, or genderqueer; were assigned male sex at birth; are taking or initiating PrEP; own a smartphone;

understand and read English or Spanish; have a self-reported history of sex with men in the past 12-months; and live in the NYC or Birmingham, AL areas. Participants may identify as any race or ethnicity, but to ensure a diverse sample comprised mainly of racial/ethnic minority participants, the study will utilize recruitment controls to enroll at least 50% African American/Black and/or Hispanic/Latino participants. Patient participants will be recruited to the study through a combination of approaches including flyers and social media, referral, in-person outreach, and through word of mouth. Rolling enrollment will continue until enrollment targets are reached. Each Aim 1 participant will be followed for 12 months. All participants will receive PrEP clinical services congruent with CDC PrEP guidelines. Participants using oral PrEP will receive CleverCap, an electronic medication monitoring device, that will track and support medication adherence. At the three-month study visit, participants using oral PrEP will receive the mChoice mobile phone application, an evidence-based intervention that supports PrEP use through medication monitoring, study staff interaction, and other resources. Aim 1 assessments include: a baseline survey of self-reported demographic factors, sexual and drug use behaviors, and potential cofactors of sexual and drug use behavior including attitudes, beliefs, knowledge, traits, and other psychosocial factors; follow-up surveys at 3-, 6-, 9-, and 12-month study visits which will assess experiences with PrEP, PrEP adherence, and behavioral and social factors;

medication adherence data from CleverCap; participant use and voluntary self-reported adherence and HIV exposure risk-related data from the mChoice app; PrEP clinical care data from clinic electronic medical records; and urine studies assessing PrEP adherence. The information collected in Aim 1 will be used to evaluate the effectiveness of the mChoice intervention to improve PrEP adherence and persistence, and to increase understanding of PrEP experiences and factors that influence PrEP choices among MSM in clinical settings.

Aim 2 of the study will enroll 30 YMSM who participated in Aim 1; 15 from New York and 15 from Alabama. Participants will be recruited at Aim 1 study visits. Study staff will conduct in-depth interviews with Aim 2 participants exploring their experiences with PrEP, reasons for PrEP choices, and thoughts about the mChoice intervention. Data collected in Aim 2 will contribute to the evaluation of the mChoice intervention, implementation, and contribute to understanding factors that influence PrEP choices by MSM in clinical settings.

Aim 3 of the study will include 20 health care providers (10 from New York and 10 from Alabama) involved in the direct delivery of PrEP services at participating clinical sites. Providers may include nurse practitioners, physicians, PrEP coordinators/navigators, medical assistants, and other cross-trained coordinators from the participating clinics. Providers will be recruited via flyers, emails to clinic staff, and referrals. Providers will receive education and training

designed to improve knowledge of PrEP options and clinical recommendations and enhance provider communications with patients. Aim 3 includes practice facilitation, an intervention that includes identification of a clinic champion who will engage other providers in embracing PrEP recommendations, as well as ongoing support from a practice coach who will offer tools, resources, hands-on guidance, and content expertise to assist the clinic team in developing strategies to improve clinical PrEP services. Aim 3 assessments include notes from practice facilitation coaching sessions; in-depth interviews of participating providers exploring their experiences with the intervention and thoughts about providing PrEP clinical services; and a clinic assessment completed by clinic staff every six months to describe the current implementation of PrEP services at their clinical site. These data will inform ongoing practice improvement in PrEP clinical services and increase understanding of provider experiences with providing PrEP clinical services.

It is expected that half of screened persons will meet study eligibility. For all Aims we anticipate that screening and completion of the locator form will each take five minutes. Study staff will assist Aim 1 participants with onboarding the CleverCap device and mChoice app, a process that will take 20 minutes. Aim 1 participants will complete the baseline survey once (anticipated 30 minutes completion time) and the follow-up survey four times (anticipated completion time 30 minutes each)

over their 12-month participation period. Total study enrollment for Aim 1 is 400, over the three-year data collection period the estimated annual enrollment is 134. Aims 2 and 3 interviews will take 60 minutes to complete. For Aim 2, total study enrollment is 30, over the three-year data collection period the estimated annual enrollment is 10. For Aim 3, total study enrollment is 20, over the three-year data collection period the estimated annual enrollment is seven. Additionally, a single Aim 3 participant at each of the four participating clinic sites will complete a clinic assessment form every six months throughout the study period.

The total number of burden hours is 1,323 across 36 months of data collection. The total estimated annualized burden hours are 441. There are no costs to the participants other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Aim 1 participants - YMSM General public, adults	Aim 1 Participant Eligibility Screener	268	1	5/60	22
Aim 1 participants - YMSM General public, adults	Aim 1 Participant Locator Form	134	1	5/60	12
Aim 1 participants - YMSM	Aim 1 mChoice	134	1	20/60	45

General public, adults	Onboarding Guide				
Aim 1 participants – YMSM General public, adults	Aim 1 Participant Baseline Survey	134	1	30/60	67
Aim 1 participants – YMSM General public, adults	Aim 1 Participant Follow-up Survey	134	4	30/60	268
Aim 2 participants – YMSM General public, adults	Aim 2 Participant Eligibility Screener	20	1	5/60	2
Aim 2 participants – YMSM General public, adults	Aim 2 Participant Locator Form	10	1	5/60	1
Aim 2 participants – YMSM General public, adults	Aim 2 Participant Interview Guide	10	1	1.0	10
Aim 3 participants – providers General public, adults	Aim 3 Participant Eligibility Screener	14	1	5/60	2
Aim 3 participants – providers General public, adults	Aim 3 Participant Locator Form	7	1	5/60	1
Aim 3 participants – providers General public, adults	Aim 3 Participant Interview Guide	7	1	1.0	7
Aim 3 participant – clinic	Aim 3 Clinic Assessment	4	2	30/60	4

staff respondent, 1 per clinic site					
General public, adults					
TOTAL					441

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